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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,868	12/11/2003	Randy Westlund	GUID.076PA (02-046)	8097

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MINNEAPOLIS, MN 55425

EXAMINER
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JASTRZAB, JEFFREY R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p>Application No. 10/733,868</p>	<p>Applicant(s) WESTLUND, RANDY</p>	
	<p>Examiner Jeffrey R. Jastrzab</p>	<p>Art Unit 3762</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 30 March 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

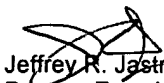
3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: \_\_\_\_\_.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

  
 Jeffrey R. Jastrzab  
 Primary Examiner  
 Art Unit: 3762  
 4/7/06

## ADVISORY ACTION

### *Response to Arguments*

Applicant's arguments filed 3/30/06 have been fully considered but they are not persuasive.

Specifically, Applicant's arguments with respect to Salo et al. relate to the insulated tip of the helical electrode. Applicant argues, in part, that

*"Salo clearly teaches that the portion of its electrode covered by insulation does not define a tissue stimulating portion of the electrode. Salo explicitly defines its electrode surface" as the bare distal convolutions shown in the Figures and described in the text see, e.g., column 1, lines 59-62). The covered portion of the Salo electrode can not define a tissue stimulating surface, as this would frustrate the purpose of the disclosed electrode (i.e., this would result in stimulating both the right and left ventricles, which the Salo electrode is designed to avoid)."*

A representative portion of the claim language in question can be found in Claim 1 as follows:

"a fluoropolymer coating or sleeve provided on a majority of an exposed surface of the active fixation arrangement sufficient in coverage to inhibit exit block development".

Salo et al. clearly teaches a coating on a majority of the surface of the active fixation arrangement as only a portion, i.e. the distal tip is uncovered. What appears to be the real issue is the meaning of "exposed surface". Looking to Applicant's specification, the exposed surface is referred to as one of several options as follows:

*"layer 425 thereby typically covers most or all of the exposed helical electrode 420, but may alternately include voids, apertures, or other discontinuities. The polymer layer 425 solicits less tissue inflammation and reduces the amount of fibrotic tissue around the implant site, reducing exit block development"*


It is precisely the "voids, apertures, or other discontinuities" embodiment that allows the Salo et al. structure to read on the claims as written. Salo et al. amounts to an active electrode that has insulation covering most of the exposed or active portion and a void or discontinuity in the insulation that makes the distal tip open to stimulate. Clearly this insulation covers part of the active surface such that exit block is inhibited in the insulated region. The claims do not call for the entire active surface to be covered with the coating, while still allowing active stimulation, and also inhibiting exit block. It would appear that in order to address that feature, some delineation between insulation and a coating that allows electricity to pass through it, either by its thickness or its discontinuities on a conductor would need to be claimed. Such a feature, however has not been claimed nor searched to date.

Applicant's arguments as to the combination with Helland are noted, however, since they attack the combination on the structural basis of Helland rather than on whether or not the substitution of known functionally equivalent insulators is proper, the arguments are deemed to be moot.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Jastrzab whose telephone number is (571) 272-4947. The examiner can normally be reached on M-W 5:30 a.m. to 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey R. Jastrzab  
Primary Examiner  
Art Unit 3762

4/7/02